Attorney Docket No. 125889.00101 Page 1 of 20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Jeffrey E. FETTERMAN, et al.

Confirmation No.: 6372

Application No.: 10/722,262

Group Art Unit: 3686

Filed: November 25, 2003

Examiner: Rajiv J. Raj

Title: A METHOD OF ASSESSING AND MANAGING RISKS ASSOCIATED WITH A

PHARMACEUTICAL PRODUCT

PRELIMINARY AMENDMENT

Mail Stop Amendment Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir

This Preliminary Amendment, together with the Request for Continued Examination and the Petition for an Extension of Time, constitutes a complete reply to the Final Office Action mailed December 7, 2009 in the above-identified application. The following remarks are respectfully submitted.

Amendments to the Claims begin on page 2.

Remarks begin on page 12.